K082567

OCT 3 - 2008

Summary of Safety and Effectiveness
Stryker® Compartmental Knee System Line Extension

Proprietary Name:	Stryker® Compartmental Knee System Line Extension
Common Name:	Knee Prosthesis
Classification Name and Reference:	Knee joint femortotibial polymer/metal semi constrained cemented prosthesis. 21 CFR §888.3530 Knee joint patellofemoral polymer/metal semi constrained cemented prosthesis. 21 CFR §888.3540 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis. 21 CFR §888.3520 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis. 21 CFR §888.3530
Device Product Code:	87 NPJ, 87 KRR, 87 HSX, 87 HRY
For Information Contact:	Francisco Haro, Sr. Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	September 3, 2008

Description:

The Stryker® Compartmental Knee System consists of sterile, single-use components intended for replacement of the femoral side of the patellofemoral joint and/or the condyle region(s) of the femoral joint as needed. The system includes patellofemoral, femoral, and tibial components from currently marketed Howmedica Osteonics' knee systems for patellofemoral and unicondylar arthroplasty. The system allows the physician to choose the most appropriate option to treat the patient with patellofemoral arthroplasty and/or unicondylar arthroplasty as needed.

Intended Use:

The Stryker® Compartmental Knee System Line Extension consists of sterile, single-use devices intended for replacement of the patellofemoral joint and/or the condyle region(s) of the femoral joint as needed. The Stryker® Compartmental Knee System Line Extension includes Triathlon® PKR femoral condyle regions for either the right or left knee.

Indications for Use:

The Stryker® Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicondylar arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker® Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis, or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement only.

Substantial Equivalence:

The device is substantially equivalent to its predicates for patellofemoral arthroplasty and femorotibial arthroplasty in regards to intended use, design, materials, and operational principles. The analysis demonstrated that the components from these systems are compatible when used for patellofemoral and/or femorotibial replacement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 - 2008

Mr. Francisco Haro
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K082567
Trade/Device Name: Stryker® Compartmental Knee System Line Extension
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Codes: HRY, NPJ, HSX, KRR
Dated: September 3, 2008
Received: September 4, 2008

Dear Mr. Francisco Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K082567

Device Name: Stryker® Compartmental Knee System Line Extension

Indications for Use:

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These components are single use only and are intended for implantation with bone cement.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082567

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: _____